I. The Rejection under 35 U.S.C. §112

The Examiner has rejected claims 1-7 under 35 U.S.C. §112, second paragraph, alleging that the claims are indefinite for failing to point out and distinctly claim the subject matter which Applicants regard as the invention. Examiner indicates that in claim 1, an interferent is a relative thing since it interferes with the analysis of another component of a sample, and since there is no analyte in claim 1, the process is either lacking steps relating to the analysis of the analyte or the interferent is actually the analyte for claim 1 and the claims which depend therefrom. This rejection is respectfully traversed.

Claim 1 is directed to measuring the concentration of an interferent in a specimen. A specimen, such as the serum or plasma of whole blood, may contain components such as interferents and analytes. (See page 1, line 1 through page 2, line 10; and see page 4, line 11; page 18, line 23 to page 20, line 16; and Tables 4 and 5). Non-limiting examples of interferents include haemoglobin, bilirubin, biliverdin, light scattering substances and blood substitutes, as defined in the specification on page 1, line 21 to page 2, line 10. Examples of analytes include, but are not limited to, Na, K, Cl, HCO_3, Ca, Mg, Creat (Creatine), Urea, Glu (glucose), TProt (total protein), AST (aspartate amino transferase), GGT (gama glutamyl trasnferase), LDH (lactate dehydrogenase), CK (creatin kinase), ALP (alkaline phosphatase) and TBili (total bilirubin). Thus, an interferent is simply a compound present in a specimen and the concentration of an interferent in a specimen can be determined just as any other compound in a specimen.

By measuring the concentration of an interferent within the specimen, corrected readings for an analyte may also be obtained. However, the determination of the concentration of an interferent may be carried out together with, or independent from, the determination of the concentration of an analyte. Claim 1 is directed to determining the concentration of an interferent in a specimen. It is respectfully submitted that independent claim 1, and dependent claims 3, 5, 6 and 7, are in conformance with 35 U.S.C. § 112, second paragraph. Therefore, withdrawal of the rejection of claims 1, 3, and 5-7 is respectfully requested.

Claims 2 to 4 have been cancelled without prejudice, and the subject matter of these claims introduced in new independent claims 19 to 21, respectively. Therefore, withdrawal of the rejection of claims 2 and 4 is respectfully requested.

II. The Rejection under 35 U.S.C. § 103

The Examiner rejected claims 1-18 under 35 U.S.C. § 103(a), as being unpatentable over Sagusa in view of Christenson, Leissing or Mullins, Gimpel and Simon. This rejection is respectfully traversed.

As the Examiner has noted, the Sagusa patent teaches a colorimetric method for measuring components is a sample in the presence of interfering chromogens. Color former is added to blood samples for coloring, and measurements for specific components are determined based on the light absorbance caused by the coloring. However, no color former is added to blood serum samples in the methods as claimed in the present application. A person of skill in the art, desirous of identifying the presence of an interferent in the presence of a blood substitute, would not be led to method disclosed in claim 1 upon reading Sagusa, since there is no requirement to add an exogenous agent in claims 1, 8 or 17.

Christenson et al., disclose that haemoglobin based blood substitutes interfere with routine chemical tests, and the dilution of the sample is suggested as a way to avoid interference. There is no teaching or suggestion in Christenson et al., as to how an interferent may be identified and/or quantified in a blood sample comprising a blood substitute. Rather, Applicants submit that Christenson et al. help define the problem in the art that the present invention is solving, that being, determining the concentration of an interferent in a sample, and if desired, correcting for the concentration of the interferent when establishing the concentration of an analyte in the sample.

Leissing et al., disclose modifications of clinical chemistry methods to overcome interferences from diaspirin crosslinked haemoglobin (DCLHb). The abstract teaches that filtering samples through an Amicon Centrifree micropartition system can remove concentrations of DCLHb up to 5000 mg/dl, producing a filtrate with molecular weight constituents less than 30000 daltons. Furthermore, for the detection of some analytes, dilution of the sample is required, in a method similar to that disclosed in Christenson et al. Leissing et al. do not teach or suggest the subject matter that is disclosed by the claims of the instant application. Leissing, as noted for Christenson et al., define the problem in the art that the present invention is solving.

Mullins et al., teaches that fluosol may lead to potential errors in the analysis of blood specimens. There is no disclosure or suggestion as to how an interferent may be identified and/or quantified in a blood sample that comprises a blood substitute. Rather, Mullins et al. further define the problem that the present invention is addressed to solving.

Gimpel et al., discloses a method of measuring total bilirubin concentrations in cerebrospinal fluid based on diazotization of bilirubin. There is no teaching or suggestion for the determination of the concentration of an interferent in the absence of diazotization.

Simon et al., teaches that iron dextran therapy may cause a red-brown discolouration of the plasma simulating a hemolytic transfusion reaction. The method used in Simon et al. to detect the iron comprises adding Gomori's iron stain (page 342, last paragraph, left hand column) and obtaining a blue colour. There is no suggestion or disclosure in Simon et al. of a method of determining the concentration of an interferent contained in a specimen, nor to using the method as defined in claim 1 of the present application, as no exogenous reagent is added to the sample in the methods defined in claims 1, 8 or 17.

Applicant therefore submits that Sagusa, in combination with of Christenson, Leissing or Mullins, Gimpel and Simon do not teach or suggest the determination of the concentration of an interferent within a sample as claimed in claims 1, 8 or 17. Therefore, withdrawal of the rejection of claims 1-18 under 35 U.S.C. §103 (a) is respectfully requested.

Conclusion

It is respectfully submitted that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicants' attorney ((612) 349-9580) to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

JAMES SAMSOONDAR ET AL.

By their Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. Box 2938
Minneapolis, MN 55402
(612) 349-9587

Date June 3, 2002 By _____

Patti J. Jurkovich
Reg. No. 44,813

CERTIFICATE UNDER 37 C.F.R. 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Commissioner of Patents, Washington, D.C. 20231, on this 3rd day of June, 2002. (month)

Candis D Duending
Name

_____
Signature